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Tegels

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(54) **CAM DRIVEN COMPACTION TUBE FOR VASCULAR CLOSURE DEVICE**

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(51) **Int. Cl.**

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A61B 17/06	(2006.01)
A61B 17/29	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/0057*** (2013.01); *A61B 17/0482* (2013.01); *A61B 17/06123* (2013.01); *A61B 2017/00637* (2013.01); *A61B 2017/00654* (2013.01); *A61B 2017/00659* (2013.01); *A61B 2017/0414* (2013.01); *A61B 2017/0417* (2013.01); *A61B 2017/0496* (2013.01); *A61B 2017/2915* (2013.01)

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CPC A61B 17/0057; A61B 17/0401; A61B 17/0482; A61B 2017/00637; A61B 17/06123; A61B 2017/2915; A61B 2017/00654; A61B 2017/0417; A61B 2017/0496; A61B 2017/0414; A61B 2017/00659

USPC 606/213, 232, 103

See application file for complete search history.

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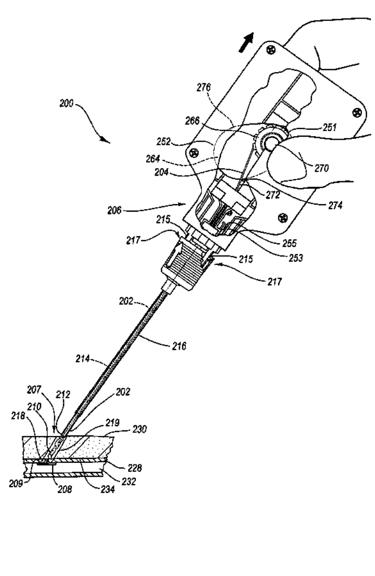
(57) **ABSTRACT**

A method and apparatus for sealing a puncture or incision formed percutaneously in a tissue. The apparatus including an anchor, a sealing plug, a filament connected between the sealing plug and the anchor, a compaction member assembly, a spool and a driving plate. The compaction member assembly being disposed adjacent the sealing plug and structured and arranged to apply an axially directed compressive force to automatically compact the sealing plug toward the anchor. The spool has a portion of the filament wound thereon. The driving plate being connected to the spool and having a cam surface portion. The cam surface portion is arranged to contact a proximal end of the compaction member assembly upon rotation of the spool to advance a distal end of the compaction member assembly.

14 Claims, 11 Drawing Sheets



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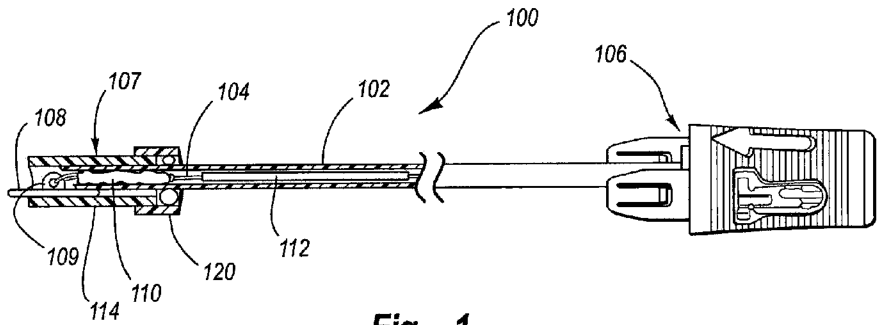

Fig. 1
(Prior Art)

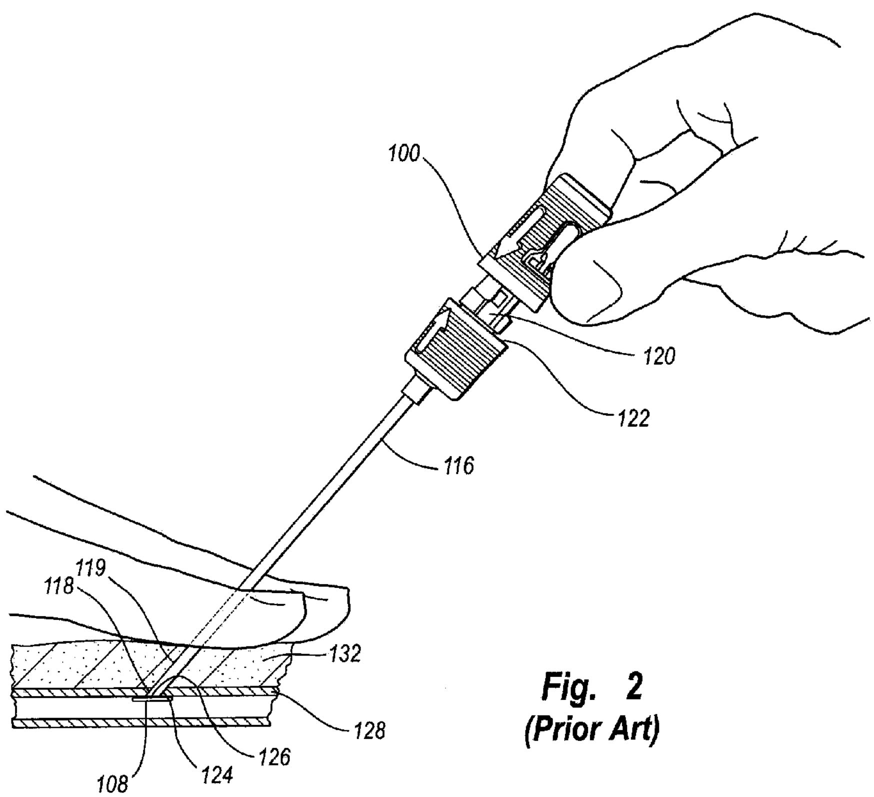

Fig. 2
(Prior Art)

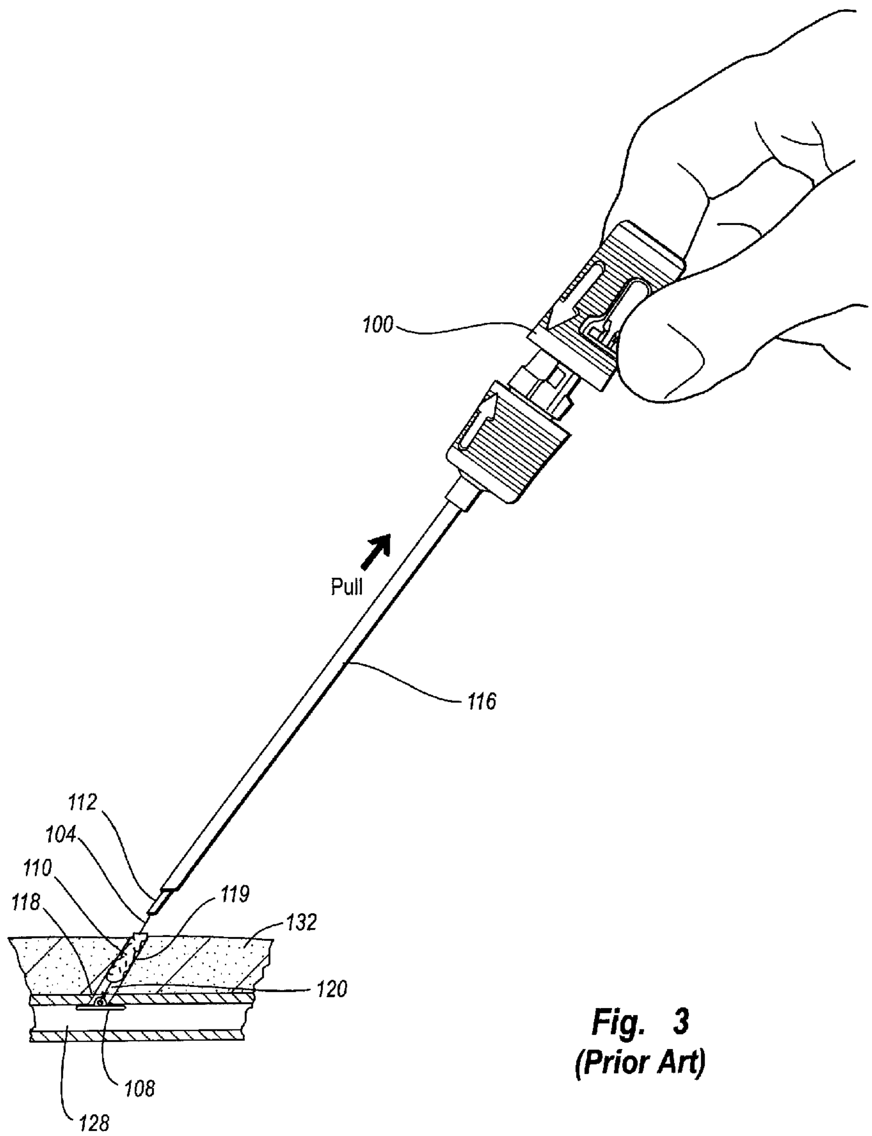

Fig. 3
(Prior Art)

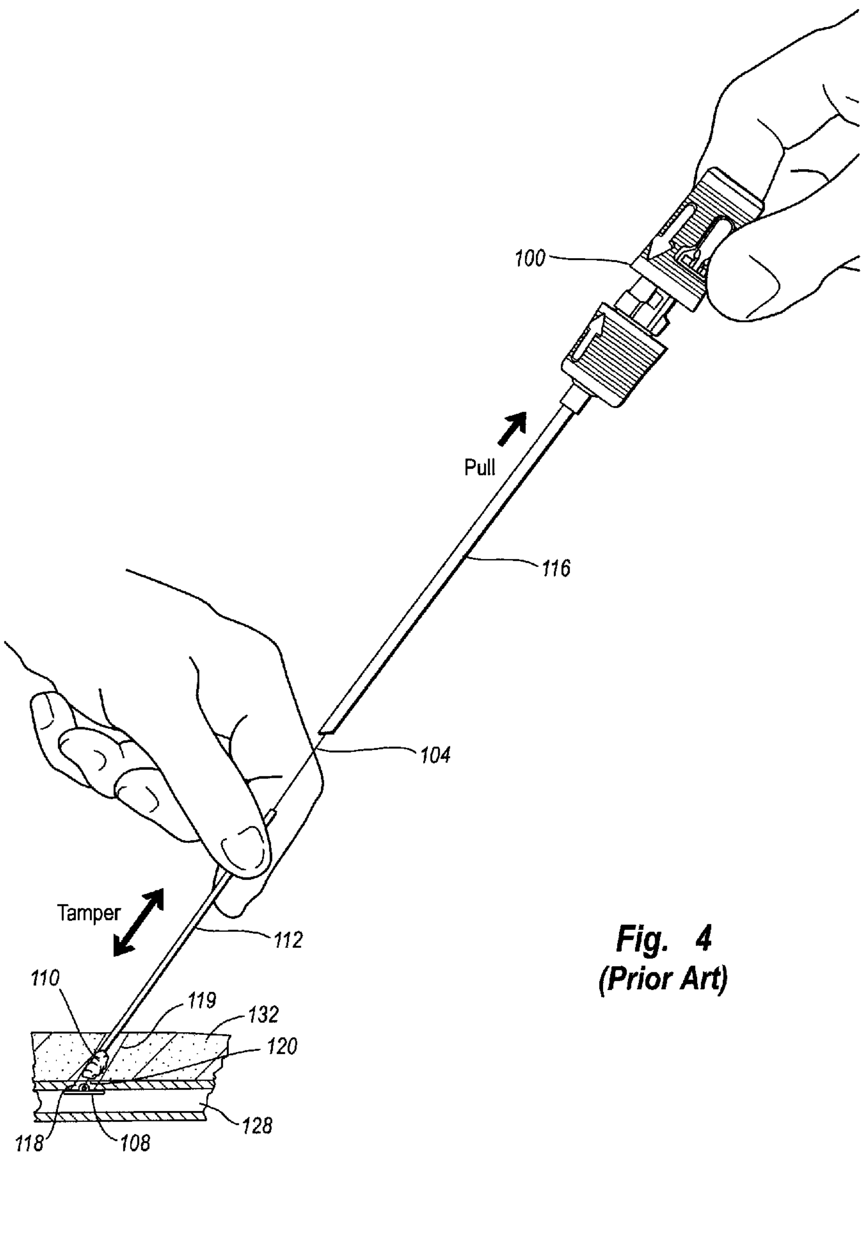

Fig. 4
(Prior Art)

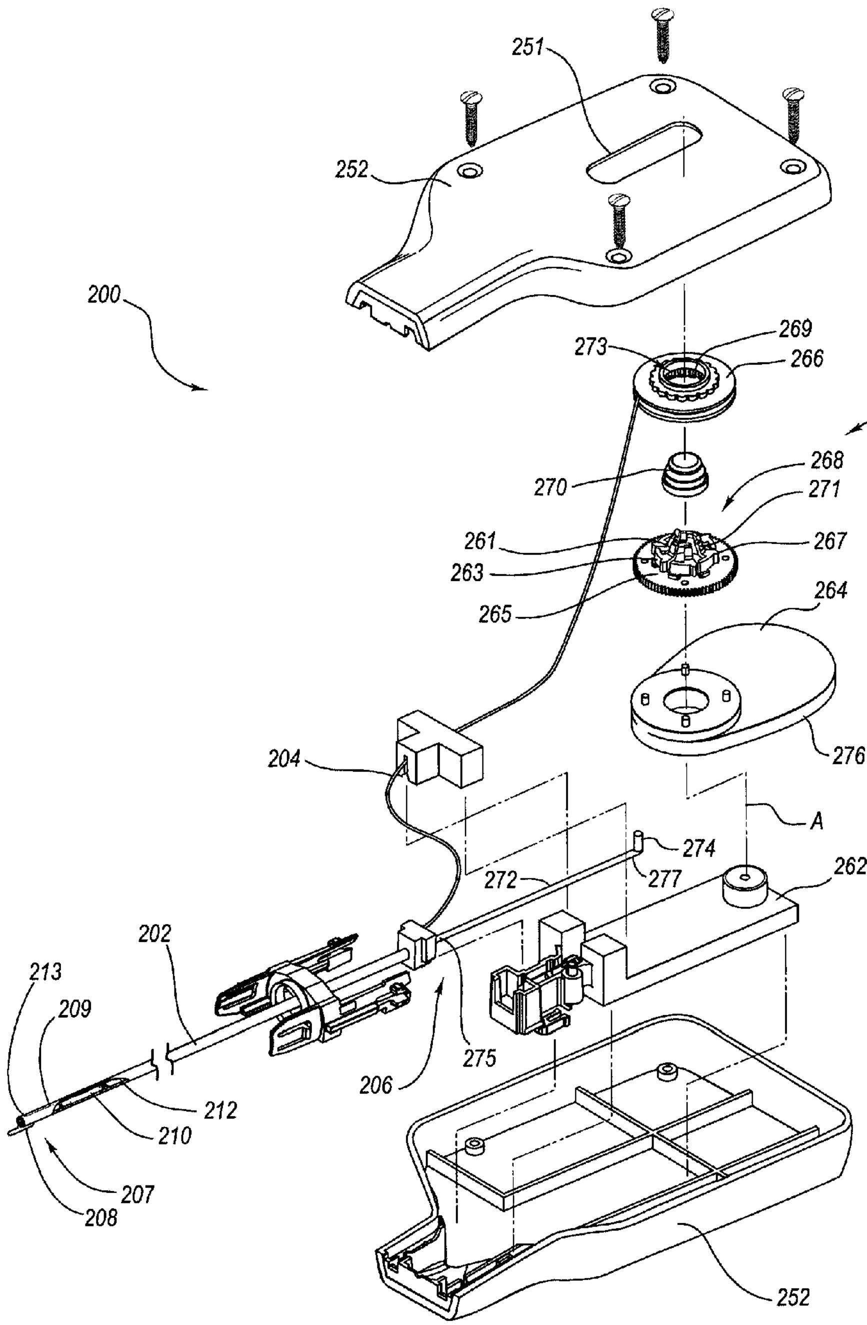

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Fig. 5A

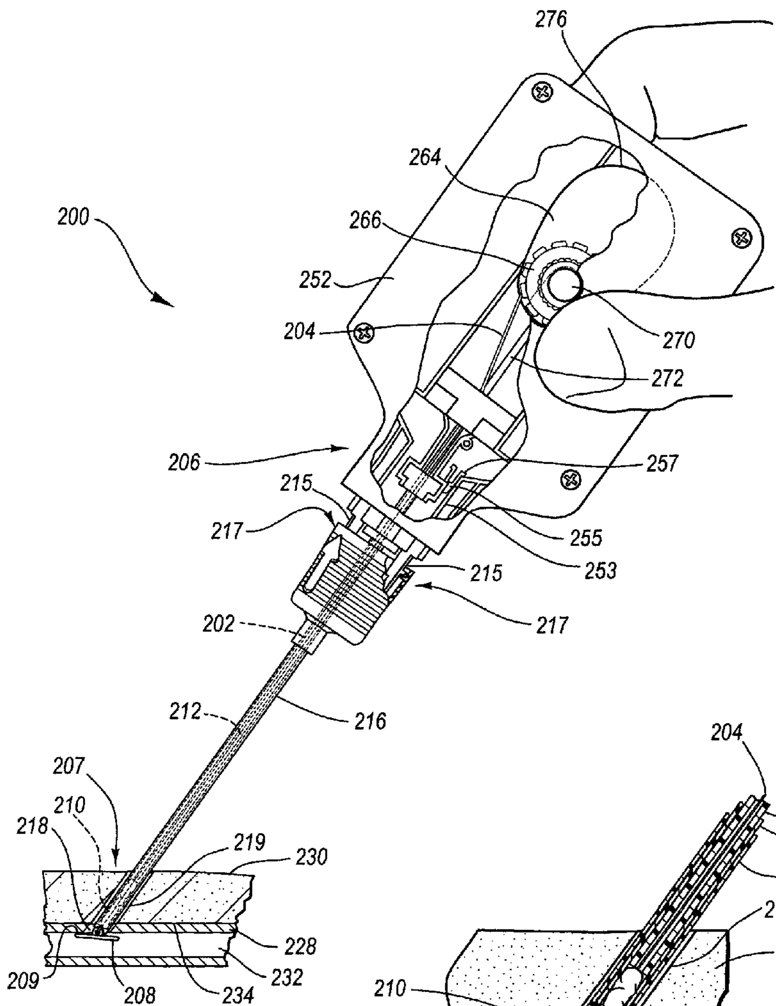
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Fig. 5B

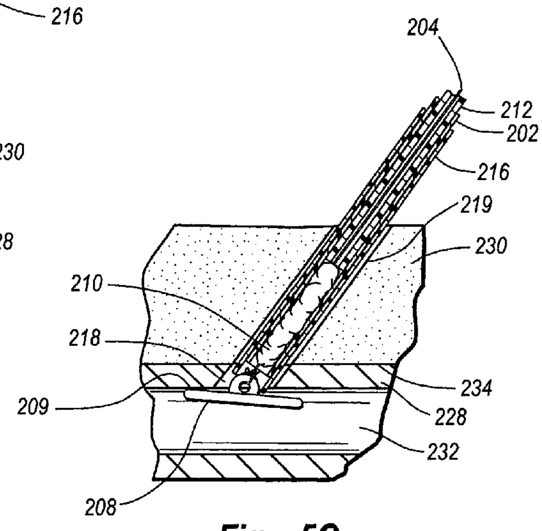
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Fig. 5C

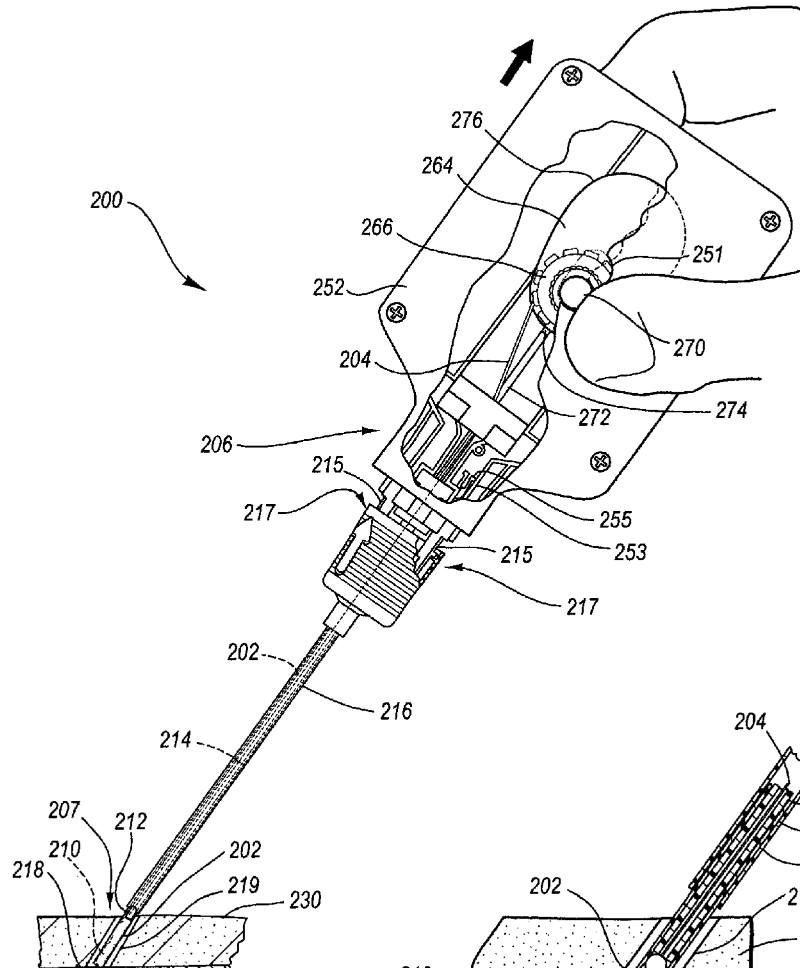
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Fig. 5D

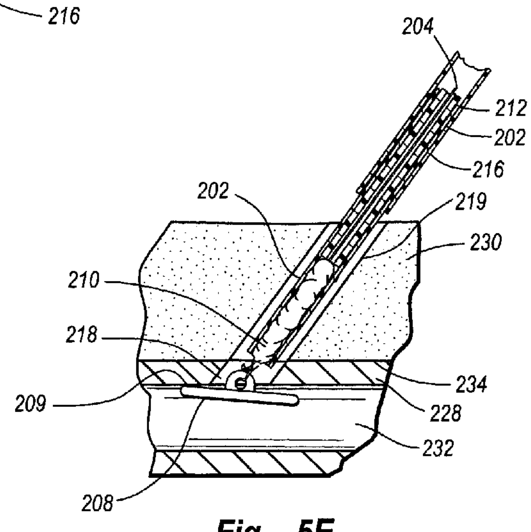
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Fig. 5E

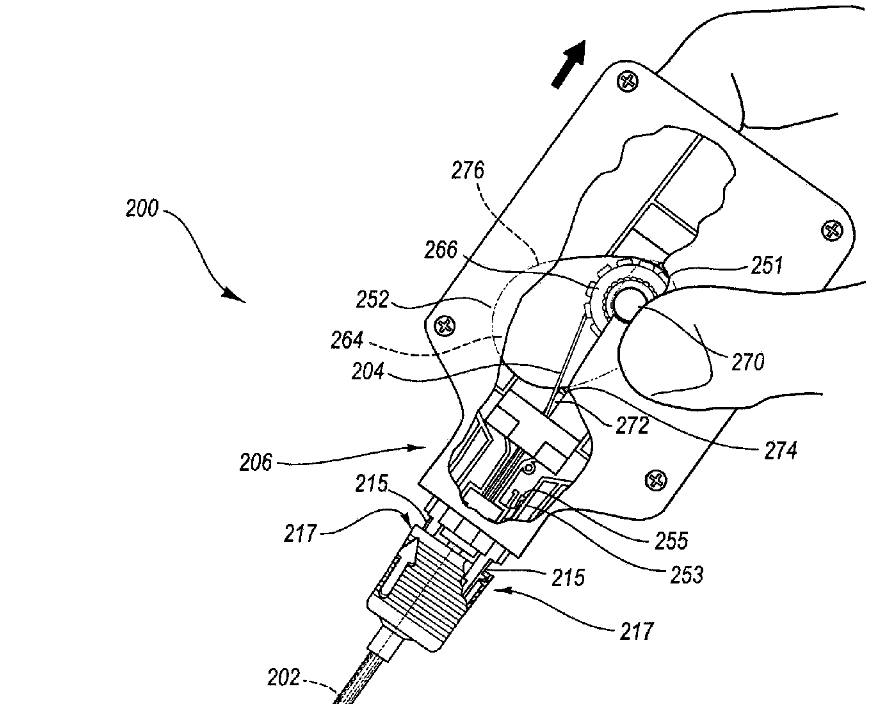
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Fig. 5F

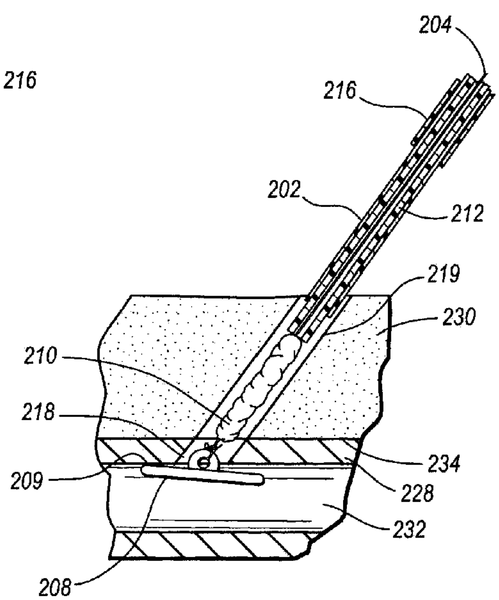
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Fig. 5G

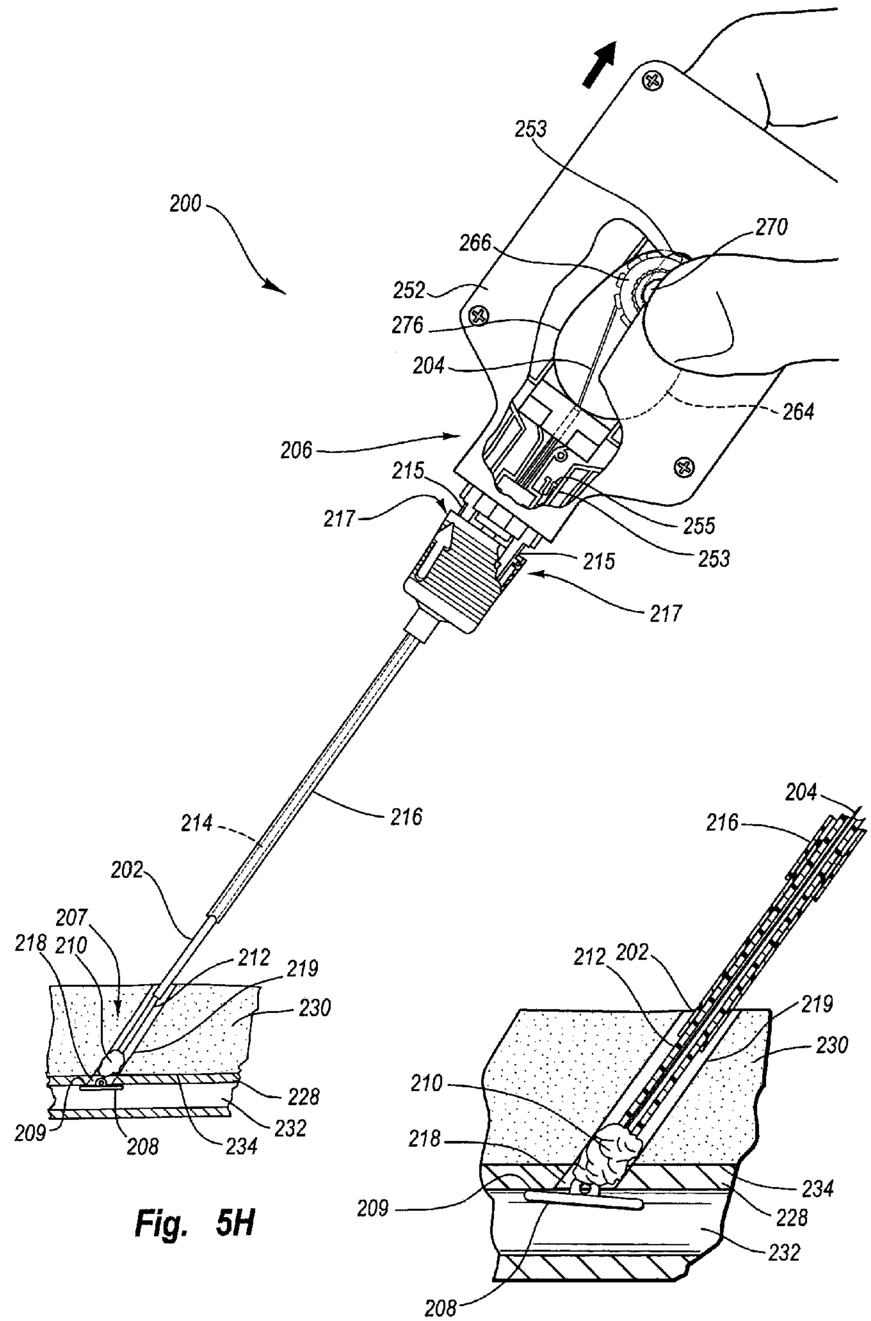
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Fig. 5H

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Fig. 5I

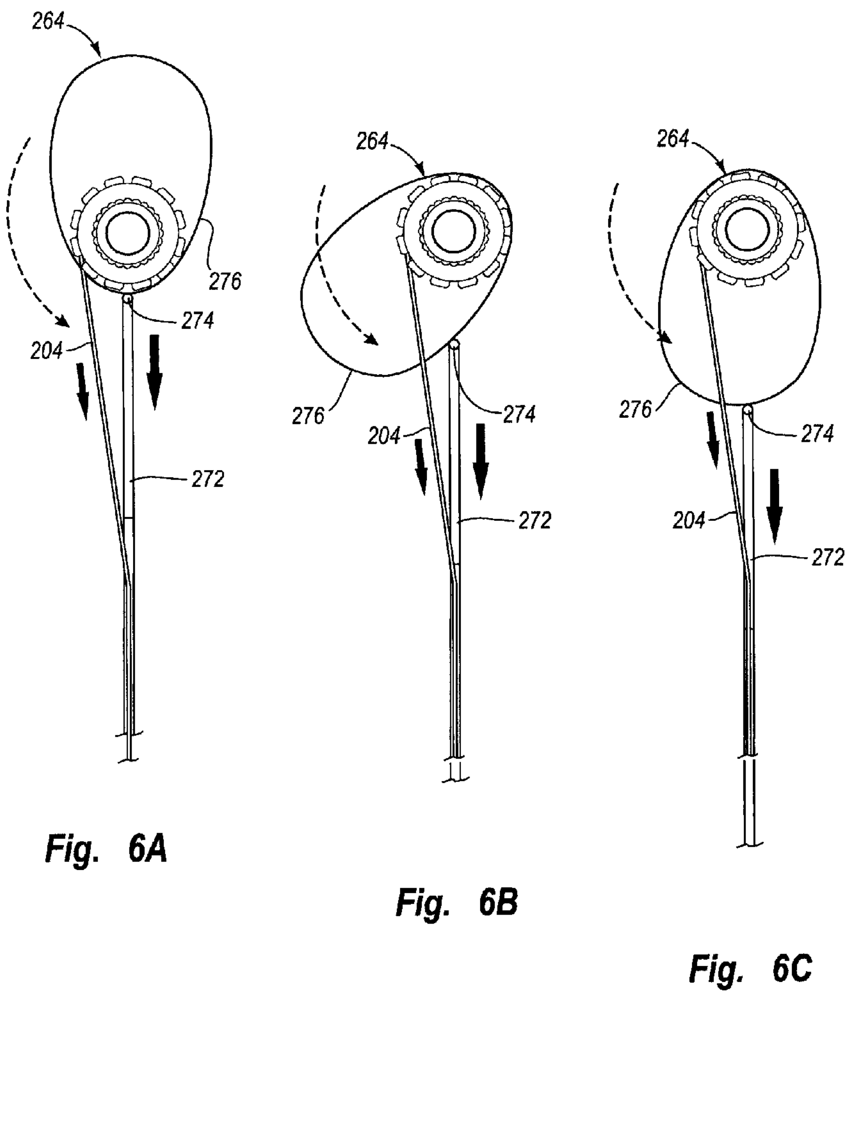

Fig. 6A

Fig. 6B

Fig. 6C

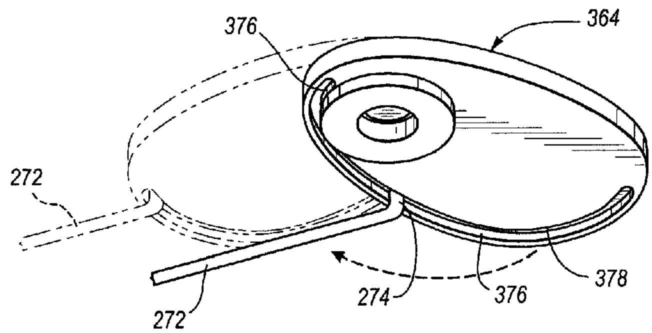

Fig. 7

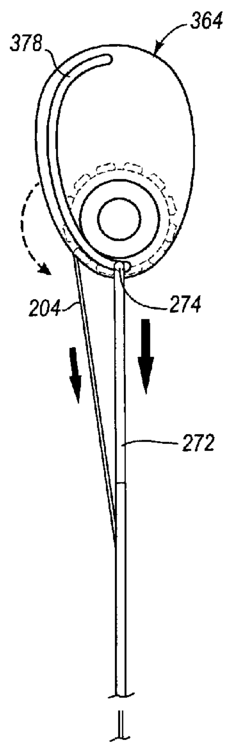

Fig. 8A

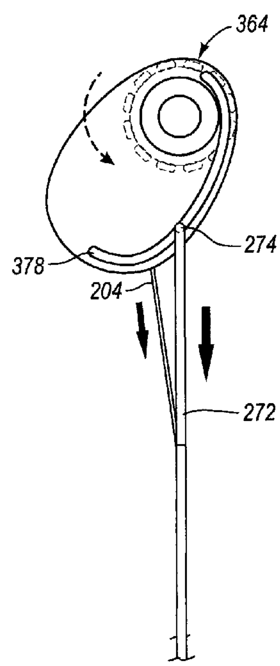

Fig. 8B

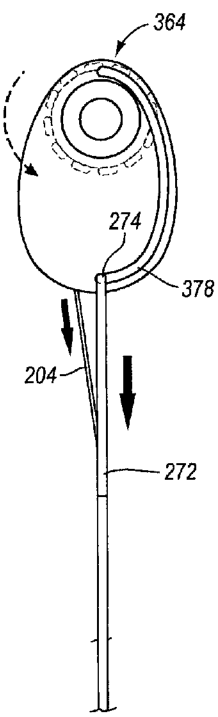

Fig. 8C

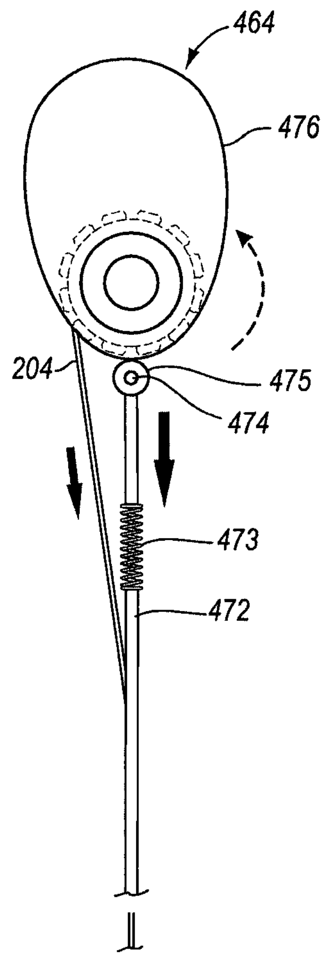

Fig. 9

CAM DRIVEN COMPACTION TUBE FOR VASCULAR CLOSURE DEVICE

TECHNICAL FIELD

The present disclosure relates generally to medical devices and more particularly to devices for sealing punctures or incisions in a tissue wall.

BACKGROUND

Various surgical procedures are routinely carried out intravascularly or intraluminally. For example, in the treatment of vascular disease, such as arteriosclerosis, it is a common practice to invade the vessel and insert an instrument (e.g., a balloon or other type of catheter) to carry out a procedure within the vessel. Such procedures usually involve the percutaneous puncture of the vessel so that an insertion sheath may be placed in the vessel and thereafter instruments (e.g., catheters) may pass through the sheath to an operative position within the vessel. Intravascular and intraluminal procedures unavoidably present the problem of stopping the bleeding at the percutaneous puncture after the procedure has been completed and after the instruments (and any insertion sheaths used therewith) have been removed. Bleeding from puncture sites, particularly in the case of femoral arterial punctures, is typically stopped by utilizing vascular closure devices, such as those described in U.S. Pat. Nos. 6,090,130 and 6,045,569, which are hereby incorporated in their entireties herein by this reference.

Typical closure devices such as the ones described in the above-mentioned patents place a sealing plug at the tissue puncture site. Successful deployment of the sealing plug, however, requires that it be manually ejected from within a device sheath and compacted down to an outer surface of the tissue puncture using a compaction tube. The compaction procedure cannot commence until the device sheath (within which the compaction tube is located) has been removed so as to expose the compaction tube for manual grasping. Under certain conditions, removal of the sheath prior to compacting the sealing plug may cause the sealing plug itself to be displaced proximally from the tissue puncture, hindering subsequent placement of the sealing plug, and resulting in only a partial seal and associated late bleeding from the tissue puncture. Accordingly, there is a need for improving the mechanism for deployment of the sealing plug at the site of a tissue puncture.

SUMMARY

The present disclosure meets the above-described needs and others. Specifically, the present disclosure provides methods and systems for closing internal tissue punctures. However, unlike prior systems, the present disclosure provides automatic compaction to a sealing plug as the closure device is retracted. In addition, the present disclosure allows the automatic compaction system to disengage, facilitating full retraction of the closure device and easy separation of the sealing plug from the remainder of the closure device.

In one of many possible embodiments, the present disclosure provides a tissue puncture closure device that includes an anchor, a sealing plug, a filament, a compaction member assembly, a spool, and a driving plate. The filament is positioned between the sealing plug and the anchor. The compaction member assembly is structured and arranged to apply an axially directed compressive force to automatically compact the sealing plug toward the anchor, and has a distal end and a

proximal end. The spool has a portion of the filament wound thereon. The driving plate is connected to the spool and has a cam surface portion that is arranged to contact the compaction member assembly upon rotation of the spool to advance the distal end of the compaction member assembly.

The cam surface portion may be defined around a periphery of the driving plate. The cam surface portion may be defined within a slot feature of the driving plate. The compaction member assembly may further include a drive follower positioned at the proximal end of the compaction member assembly and exposed for contact by the cam surface portion. The compaction member assembly may include a compaction tube and a compaction tube driver arranged end-to-end, wherein the compaction tube defines the distal end of the compaction member assembly. The cam surface portion may include a constant radius portion and a variable radius portion.

Another aspect of the present disclosure relates to a tissue puncture closure device for partial insertion into and sealing of a tissue puncture in an internal tissue wall accessible through a percutaneous incision. The tissue puncture closure device includes an anchor, a sealing plug, a filament, a compaction assembly, a storage spool, and a driving plate. The anchor is disposed on a distal side of the internal tissue wall. The sealing plug is disposed on a proximal side of the internal tissue wall. The filament is connected to and anchored at a distal end to the anchor and sealing plug, wherein the sealing plug is slidable and cinchable along the filament toward the anchor to close the tissue puncture. The compaction assembly is disposed on the filament and arranged to drive the sealing plug along the filament distally towards the anchor. The storage spool has a proximal end of the filament wound thereon. The driving plate is connected to the storage spool and has a cam surface arranged to apply a variable driving force to the proximal end of the compaction assembly upon rotation of the storage spool.

The driving plate may be connected to the storage spool by a releasable clutch. The cam surface may include a constant radius portion and a variable radius portion. The storage spool and driving plate may be arranged coaxially. The driving plate may be coupled to the compaction assembly. Withdrawing the tissue puncture closure device from the tissue puncture with the anchor bearing against the internal tissue wall may unwind the filament from the storage spool. The storage spool may rotate the driving plate and the driving plate drives the compaction assembly to directly or indirectly provide a compaction force to the sealing plug. The cam surface may directly contact the compaction assembly.

Another aspect of the present disclosure relates to a method of sealing a tissue puncture in an internal tissue wall of a vessel accessible through a percutaneous incision. The method may include providing a closure device having an anchor, a sealing plug, a filament positioned between the sealing plug and the anchor, a compaction member, a spool having a portion of the filament wound thereon, and a driving plate that is connected to the spool and has a cam surface portion. The method further includes inserting the anchor through the tissue puncture and withdrawing the closure device from the tissue puncture with the anchor positioned within the vessel. Withdrawing the closure device rotates the spool, and rotating the spool rotates the driving plate to advance the compaction member and compact the sealing plug toward the anchor.

Rotating the driving plate may contact the cam surface portion with a proximal end portion of the compaction member to apply a variable force to the compaction member. The closure device may further include a compaction member assembly that includes a compaction tube having a distal end arranged adjacent to the sealing plug, and a compaction tube driver having a distal end abutting a proximal end of the compaction tube. Rotating the driving plate contacts the cam surface portion with a proximal end of the compaction tube driver.

Another aspect of the present disclosure relates to a method of sealing a tissue puncture in an internal tissue wall accessible through a percutaneous incision. The method includes providing a tissue puncture closure device comprising a filament connected at its distal end to an anchor and to a sealing plug located proximal of the anchor for disposition and anchoring about the tissue puncture, a compaction member assembly, and a driving plate having a cam surface portion. The method also includes inserting the tissue puncture closure device into the percutaneous incision, deploying the anchor into the tissue puncture, at least partially withdrawing the tissue puncture closure device from the percutaneous incision, and automatically compacting the sealing plug toward the anchor upon withdrawal of the tissue puncture closure device from the internal tissue wall puncture with the driving plate and compaction member assembly. Automatically compacting includes rotating the driving plate to contact the cam surface portion with the compaction member assembly to advance a distal end of the compaction member assembly. The method further includes cutting the filament to leave the anchor and sealing plug at the tissue puncture.

The compaction member assembly may include a drive follower at a proximal end thereof, and the cam surface portion contacts the drive follower to advance the compaction member assembly. The tissue puncture closure device may also include a spool about which a portion of the filament is wound, wherein the spool is connected to the driving plate. Automatically compacting may include rotating the spool thereby rotating the driving plate.

Additional advantages and novel features will be set forth in the description which follows or can be learned by those skilled in the art through reading these materials or practicing the examples disclosed herein.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate various embodiments of the present disclosure and are a part of the specification. The illustrated embodiments are merely examples and do not limit the scope of the invention.

FIG. **1** is a partial cut-away view of a tissue puncture closure device according to the prior art.

FIG. **2** is a side view of the tissue puncture closure device of FIG. **1** engaged with a vessel according to the prior art.

FIG. **3** is a side view of the tissue puncture closure device of FIG. **1** being withdrawn from a vessel according to the prior art to deploy a sealing plug.

FIG. **4** is a side view of the tissue puncture closure device of FIG. **1** illustrating compaction of the sealing plug according to the prior art.

FIG. **5**A is an exploded perspective view of an example tissue puncture closure device with an automatic compaction or driving mechanism according to the present disclosure.

FIG. **5**B is a side view of the tissue puncture closure device of FIG. **5**A inserted through a procedure sheath and tissue puncture and engaged with a vessel in a first position.

FIG. **5**C is a detailed inset of FIG. **5**B.

FIG. **5**D is a side view of the tissue puncture closure device of FIG. **5**A shown engaged with a vessel in a second position with the procedure sheath retracted.

FIG. **5**E is a detailed inset of FIG. **5**D.

FIG. **5**F is a side view of the tissue puncture closure device of FIG. **5**A shown engaged with a vessel in a third position with a carrier tube retracted to expose a sealing plug adjacent to the tissue puncture.

FIG. **5**G is a detailed inset of FIG. **5**F.

FIG. **5**H is a side view of the tissue puncture closure device of FIG. **5**A engaged with a vessel in a third fourth position compacting the sealing plug.

FIG. **5**I is a detailed inset of FIG. **5**H.

FIGS. **6**A-**6**C illustrate a driving plate of the tissue puncture closure device of FIG. **5**A in three different rotated positions to advance a compaction tube driver of the tissue puncture closure device.

FIG. **7** is a perspective view of another example driving plate in accordance with the present disclosure.

FIGS. **8**A-**8**C illustrate the driving plate of FIG. **7** in three different rotated positions to advance a compaction tube driver of the tissue puncture closure device.

FIG. **9** illustrates the driving plate of FIG. **5**A with another example compaction tube driver in accordance with the present disclosure.

Throughout the drawings, identical reference numbers designate similar, but not necessarily identical, elements.

DETAILED DESCRIPTION

As mentioned above, vascular procedures are conducted throughout the world and require access to a vessel through a puncture. Most often, the vessel is a femoral artery. To close the puncture following completion of the procedure, many times a closure device is used to sandwich the puncture between an anchor and a sealing plug. However, sometimes the sealing plug is difficult to eject from the sealing device and may not properly seat against an exterior situs of the arteriotomy. If the plug does not seat properly against the arteriotomy, there is a potential for elongated bleeding.

The present disclosure describes methods and apparatuses that facilitate sealing plug ejection and proper placement of the sealing plug. One aspect of the present disclosure is directed to the use of a cam structure in a vascular closure device as part of an automatic or semi-automatic driving assembly. The cam structure may contact or be coupled to a compaction member assembly that is used to compact the sealing plug. The compaction member assembly may include a compaction tube that is arranged to contact the sealing plug. The compaction member assembly may also include a compaction tube driver positioned between the compaction tube and the cam structure. The cam structure may include at least one cam surface, and rotation of the cam structure contacts the cam surface with compaction tube driver to advance the compaction tube. The cam member may be coupled to a spool about which a portion of a suture is wound, wherein the suture is used to connect the sealing plug and an anchor of the vascular closure device together. The cam member may apply a variable driving force to the proximal end of the compaction assembly upon rotation of the spool. In some arrangements, the cam member is constructed as a driving plate that is arranged coaxially with the spool and is rotated upon rotation of the spool. A clutch may be operable between the driving plate and spool.

While the vascular instruments shown and described below include procedure sheaths and puncture sealing devices, the application of principles described herein are not limited to the specific devices shown. The principles described herein may be used with any medical device. Therefore, while the description below is directed primarily to arterial procedures and certain embodiments of a vascular closure device, the methods and apparatus are only limited by the appended claims.

As used in this specification and the appended claims, the terms "compact," "compaction," and "compacting" are used broadly to mean packing down and compressing by one or a succession of blows or taps or smooth, steady pressure, but not by excessive force. The terms "tamp" and "tamping" may relate to certain types or forms of "compaction" and "compacting." "Engage" and "engabable" are also used broadly to mean interlock, mesh, or contact between two devices. Likewise "disengage" or "disengagable" means to remove or capable of being removed from interlock, mesh, or contact. A "tube" is an elongated device with a passageway. The passageway may be enclosed or open (e.g., a trough). A "lumen" refers to any open space or cavity in a bodily organ, especially in a blood vessel. The words "including" and "having," as used in the specification, including the claims, have the same meaning as the word "comprising."

Referring to FIGS. **1**-**4**, a vascular closure device **100** is shown according to the prior art. Some example closure devices are disclosed in U.S. Published Patent Application No. 2005/0085851 and U.S. Pat. Nos. 7,618,438 and 7,618,436, which references are incorporated herein in their entirety by this reference. The vascular closure device **100** includes a carrier tube **102** with a filament or suture **104** extending at least partially therethrough. The vascular closure device **100** also includes a first or proximal end **106** and a second or distal end **107**. External to the distal end **107** of the carrier tube **102** is an anchor **108**. The anchor may include an elongated, stiff, low profile member including an eye **109** formed at the middle. The anchor **108** is typically made of a biologically resorbable polymer.

The suture **104** is threaded through the anchor **108** and back to a collagen pad **110**. The collagen pad **110** may comprise, for example, randomly oriented fibrous material bound together by chemical means. The collagen pad **110** is slidingly attached to the suture **104** as the suture passes distally through the carrier tube **102**. As the suture traverses the anchor **108** and reenters the carrier tube **102**, the suture **104** is securely slip knotted proximal to the collagen pad **110** to facilitate cinching of the collagen pad **110** when the vascular closure device **100** is properly placed and the anchor **108** deployed (see FIG. **4**).

The carrier tube **102** typically includes a compaction member **112** disposed therein. The compaction member **112** is slidingly mounted on the suture **104** and may be used by an operator to compact the collagen pad **110** toward the anchor **108** at an appropriate time to seal a percutaneous tissue puncture.

Prior to deployment of the anchor **108** within a vessel (e.g., an artery), the eye **109** of the anchor **108** rests outside the distal end **107** of the carrier tube **102**. The anchor **108** may be temporarily held in place flush with the carrier tube **102** using a bypass tube **114** that is disposed over the distal end **107** of the carrier tube **102**.

The flush arrangement of the anchor **108** and carrier tube **102** allows the anchor **108** to be inserted into a sheath such as insertion sheath **116** as shown in FIGS. **2**-**4**, and eventually through a tissue (e.g., arterial) puncture **118**. The insertion sheath **116** is shown in FIGS. **2**-**4** inserted through a percutaneous incision **119** and into a vessel **128**. The bypass tube **114** (see FIG. **1**) includes an oversized head **120** that prevents the bypass tube **114** from passing through an internal passage of the insertion sheath **116**. As the vascular closure device **100** is inserted into the insertion sheath **116**, the oversized head **120** bears against a surface **122** of insertion sheath **116**.

Further insertion of the vascular closure device **100** results in sliding movement between the carrier tube **102** and the bypass tube **114**, thereby releasing the anchor **108** from the bypass tube **114** (see FIG. **1**). The anchor **108** typically remains in the flush arrangement shown in FIG. **1** following release from the bypass tube **114**, limited in movement by the insertion sheath **116**.

The insertion sheath **116** may include a monofold at a second or distal end **126** thereof. The monofold acts as a one-way valve to the anchor **108**. A monofold is typically a plastic deformation in a portion of the insertion sheath **116** that elastically flexes as the anchor **108** is pushed out through the distal end **126** of the insertion sheath **116**. Typically, after the anchor **108** passes through the distal end **126** of the insertion sheath **116** and enters the vessel **128**, the anchor **108** is no longer constrained to the flush arrangement with respect to the carrier tube **102** and it deploys and rotates to the position shown in FIG. **2**.

The insertion sheath **116** may include a pair of closure device connection apertures (not shown) and a carrier tube aperture (not shown) at a proximal surface **122** (see FIG. **1**). The carrier tube **102** is inserted into the carrier tube aperture and the sheath connection members **130** are inserted into and releaseably engage with the closure device connection apertures when assembling the vascular closure device **100** with the insertion sheath **116**.

Referring next to FIGS. **3**-**4**, with the anchor **108** deployed, the vascular closure device **100** and the insertion sheath **116** are withdrawn together, ejecting the collagen pad **110** from the carrier tube **102** into the percutaneous incision **119** and exposing the compaction member **112**. With the compaction member **112** fully exposed as shown in FIG. **4**, the collagen pad **110** is manually compacted, and the anchor **108** and collagen pad **110** are cinched together and held in place with the self-tightening slip-knot on the suture **102**. The tissue puncture is sandwiched between the anchor **108** and the collagen pad **110**, thereby sealing the tissue puncture **118**. The suture **104** is then cut and the percutaneous incision **119** may be closed. The suture **104**, anchor **108**, and collagen pad **110** are generally made of resorbable materials and therefore remain in place while the tissue puncture **118** heals.

It may be difficult to eject and compact the collagen pad **110** using the typical vascular closure device **100** described above. The insertion sheath **116** resists deformation as the collagen pad **110** is ejected from the carrier tube and compaction does not commence until the insertion sheath **116** has been removed so as to expose the compaction member **112** for manual grasping. Under certain conditions, removal of the insertion sheath **116** prior to compacting the collagen pad **110** causes the collagen pad **110** to retract or displace proximally from the tissue puncture **118**, creating an undesirable gap between the collagen pad **110** and the tissue puncture **118**.

The general structure and function of tissue puncture closure devices used for sealing a tissue puncture in an internal tissue wall accessible through an incision in the skin are well known in the art. Applications of closure devices including those implementing principles described herein include closure of a percutaneous puncture or incision in tissue separating two internal portions of a living body, such as punctures or incisions in blood vessels, ducts or lumens, gall bladders, livers, hearts, etc.

Referring now to FIGS. **5A**-**5I**, an apparatus, for example a tissue puncture closure device **200**, is shown according to one embodiment of the present disclosure. The closure device **200** is shown in an assembly view in FIG. **5A**. FIGS. **5B**-**5I** illustrate the closure device **200** assembled and inserted through a procedure sheath **216** and into a lumen **232**. The closure device **200** has particular utility when used in connection with intravascular procedures, such as angiographic dye injection, cardiac catheterization, balloon angioplasty and other types of recanalizing of atherosclerotic arteries, etc. as the closure device **200** is designed to cause immediate hemostasis of the blood vessel (e.g., arterial) puncture. However, it will be understood that while the description of the preferred embodiments below are directed to the sealing off of percutaneous punctures in arteries, such devices have much more wide-spread applications and may be used for sealing punctures or incisions in other types of tissue walls as well. Thus, the sealing of a percutaneous puncture in a vessel, shown herein, is merely illustrative of one particular use of the closure device **200** according to principles of the present disclosure.

The closure device **200** includes a first or proximal end portion **206** and a second or distal end portion **207**. A carrier tube **202** extends from the proximal end portion **206** to the distal end portion **207** and includes an outlet **213** at the distal end portion **207**. The distal end portion **207** may include a slit **209**.

The carrier tube **202** may be made of plastic or other material and is designed for insertion through the procedure sheath **216**. The procedure sheath **216** is designed for insertion through a percutaneous incision **219** in a tissue layer **230** and into the lumen **232**. According to FIGS. **5**B-**5**I, the lumen **232** comprises an interior portion of a vessel **228** (e.g., a femoral artery).

At the distal end portion **207** of the carrier tube **202** there is an anchor **208** and a sealing plug **210**. The anchor **208** of the present embodiment is an elongated, stiff, low-profile member arranged to be seated inside the vessel **228** against a vessel wall **234** contiguous with a tissue puncture **218**. The anchor **208** is preferably made of a biologically resorbable polymer. The sealing plug **210** is formed of a compressible sponge, foam, or fibrous mat made of a non-hemostatic biologically resorbable material such as collagen, and may be configured in any shape so as to facilitate sealing the tissue puncture **218**.

The sealing plug **210** and anchor **208** are connected to one another by a connector such as a filament or suture **204** that is also biologically resorbable. The anchor **208**, the sealing plug **210**, and the suture **204** may be collectively referred to as the "closure elements" below. As shown in FIG. **5**A, the anchor **208** is initially arranged adjacent to and exterior of the distal end portion **207** of the carrier tube **202**, while the sealing plug **210** is initially disposed within the carrier tube **202**. The anchor **208** is shown nested in its low profile configuration along the carrier tube **202** to facilitate insertion into the lumen **232** in FIG. **5**A, and deployed abutting the vessel wall **234** in FIGS. **5**B-**5**I.

The suture **204** extends distally from the proximal end portion **206** of the closure device **200** through the carrier tube **202**. The suture **204** may be threaded through one or more perforations in the sealing plug **210**, through a hole in the anchor **208**, and proximally back toward the carrier tube **202** to the sealing plug **210**. The suture **204** is preferably threaded again through a perforation or series of perforations in the sealing plug **210**. The suture **204** may also be threaded around itself to form a self-tightening slip-knot. The suture **204** may thus connect the anchor **208** and the sealing plug **210** in a pulley-like arrangement to cinch the anchor **208** and the sealing plug **210** together when the carrier tube **202** is pulled away from the anchor **208** and the sealing plug **210**. The anchor **208** and the sealing plug **210** sandwich and lock together with the suture **204**, sealing the tissue puncture **218**.

The carrier tube **202** may house a compaction device or compaction member, such as a compaction tube **212**, for advancing the sealing plug **210** along the suture **204** and toward the anchor **208**. The compaction tube **212** is shown located partially within the carrier tube **202** and proximal of the sealing plug **210**. The compaction tube **212**, however, may also extend through a handle or housing **252** of the closure device **200**. The compaction tube **212** is preferably an elongated tubular or semi-tubular member that may be rigid or flexible and formed of any suitable material. For example, according to one embodiment, the compaction tube **212** is made of polyurethane. The suture **204** extends through at least a portion of the compaction tube **212**. For example, as shown in FIGS. **5**A-**5**I, the suture **204** extends along the compaction tube **212** between the proximal and distal end portions **206**, **207**. However, the suture **204** is not directly connected to the compaction tube **212**. Accordingly, the suture **204** and the compaction tube **212** may slide past one another.

According to the embodiment of FIGS. **5**A-**5**I, the suture **204** attaches to an automatic driving assembly **260**. The automatic driving assembly **260** may include a base **262**, a driving plate **264**, a spool **266**, and a clutch **268**. The driving plate **264** includes a cam feature such as a cam surface **276**. The cam surface **276** may be defined around a periphery surface of the driving plate **264**. The cam surface **276** may include a curved or contoured portion. Portions of the cam surface **276** may track a circular curvature. Other portions of the cam surface **276** may track an elliptical, oblong, or other shaped curvature. Typically, the cam surface **276** has a change of curvature (i.e., a change of radius) along its length that provides a cam action when contacted and followed by a cam follower.

The driving plate **264**, spool **266**, clutch **268**, and release member **270** may rotate about a common rotation axis A (see FIG. **5**A). FIGS. **5**A-**5**I illustrate a driving plate **264**, spool **266** and clutch **268** that rotate counter clockwise about the rotation axis A. The cam surface **276** is typically not concentric about the rotation axis A (i.e., driving plate **264** is eccentrically mounted relative to rotation axis A). As the driving plate **264** rotates, the construction of the cam surface **276** provides driving of the compaction tube **212** with a variable driving or compaction force. A rotational force provided by unwinding the suture **204** from the spool **266** is translated into the variable driving or compaction force at an interface between the cam surface **276** and the compaction assembly (e.g., at least one of the compaction tube **212** and the compaction tube driver **272** described below).

The automatic driving assembly **260** may also include a release member **270** and a compaction tube driver **272**. The release member **270** may extend through a release member opening or slot **251** of the housing **252** to be accessible by an operator of the closure device **200**. The release member opening **251** may be sized to permit some longitudinal movement of the release member **270** relative to the housing **252**. Actuation of the release member **270** may permit free unwinding of the suture **204** from the spool **266** without further compacting of the sealing plug **210**.

The compaction tube driver **272** includes distal and proximal ends **275**, **277**. The distal end **275** may abut the compaction tube **212** (e.g., at a proximal end of the compaction tube **212**). A driver follower **274** may be positioned at the proximal end **277** of the compaction tube driver **272**. The driver follower **274** may be arranged in the housing **252** adjacent the cam surface **276** so that rotation of the driving plate **264** results in contact between the cam surface **276** and the driver follower **274**. The cam construction of cam surface **276** results in application of a linear force to the compaction tube driver **272** through the driver follower **274** to advance the compaction tube **212** toward the sealing plug **210**.

In some arrangements, the automatic driving assembly **260** may include the compaction tube **212**. The compaction tube **212** and compaction tube drive **272** may together define a compaction tube assembly. The compaction tube assembly may be positioned proximal of and adjacent to the sealing plug **210**. The entire automatic driving assembly **260**, including the compaction tube **212**, may move together longitudinally relative to the housing **252**.

The automatic driving assembly **260** may be located within the housing or housing **252** at the proximal end portion **206** of the closure device **200**. Embodiments of the automatic driving assembly **260** may be selectively disengagable. For example, operation of the release member **270**, which is accessible through the release member opening **251** in the housing **252**, may release the spool **266** to permit unspooling of the suture **204**. Unspooling of the suture **204** after compaction of the sealing plug **210** permits the operator to cut the suture at a location proximal of the sealing plug **210**.

As shown in FIG. **5**A, the driving plate **264** may be connected to the spool **266**. The suture **204** is connected to and partially wound about the spool **266**. The driving plate **264** tends to rotate at the same angular rate as the spool **266**. A clutch **268** may selectively connect and release the driving plate **264** relative to the spool **266**. One embodiment of the clutch **268** is described in detail below. However, any clutch may be operable between the driving plate **264** and spool **266**.

Withdrawal of the closure device **200** from the tissue puncture **218** (if the anchor **208** is deployed and the automatic driving assembly **260** has contacted the stop (see FIGS. **5**F and **5**H)) causes the suture **204** to unwind from the spool **266**. The spool **266** rotates as the suture **204** unwinds and provides a torsional motive force that is transduced to a linear compaction force.

The torsional motive force provided by the spool **266** is transduced into the linear compaction force interaction between the driving plate **264** and compaction tube driver **272**. The driving plate **264** may be arranged coaxially with the spool **266**. When the spool **266** rotates, it drives the driving plate **264**, which in turn drives the compaction tube driver **272**. The compaction tube driver **272** drives the compaction tube **212**, which in turn compacts the sealing plug **210**.

The compaction tube **212** is preferably tubular or semi-tubular and partially disposed about the suture **204** along its longitudinal axis. The compaction tube driver **272** may comprise at least portions of the compaction tube **212**. The compaction tube driver **272** may comprise a semi-tubular shape having a generally U-shaped cross section, to provide a trough through which the suture **204** may enter and exit laterally. An open trough would permit the suture and the compaction tube driver **272** to merge as the spool **266** unwinds. Accordingly, with the anchor **208** deployed, as the closure device **200** is retracted in a first direction the suture **204** unwinds from the spool **266**, which drives the driving plate **264**. The driving plate **264** drives the compaction tube driver **272** and the compaction tube driver **272** drives the compaction tube **212** in a second direction that is opposite the first direction. The compaction tube **212** compacts the sealing plug **210**.

In practice, the carrier tube **202** of the closure device **200** (containing the closure elements described above) is inserted into the procedure sheath **216**, which is already inserted within the vessel **228** (see FIGS. **5**B-**5**C). As the closure device **200** and the associated closure elements are inserted into the procedure sheath **216**, the anchor **208** passes through and out of the distal end of the procedure sheath **216** and is inserted into the lumen **232**. As mentioned above and shown in FIG. **5**A, the anchor **208** is initially arranged substantially flush with the carrier tube **202** to facilitate insertion of the anchor **208** through the percutaneous incision **219** and into the lumen **232**.

After the anchor **208** passes out of the distal end of the procedure sheath **216**, however, the anchor **208** tends to deploy or rotate to the position shown in FIGS. **5**B-**5**C. The closure device **200** may be partially withdrawn from the procedure sheath **216**, catching the anchor **208** on the distal end of the procedure sheath **216** and rotating the anchor **208** into the position shown in FIGS. **5**B-**5**C. The closure device **200** preferably includes a pair of biased fingers **215** that are lockingly received by a matching pair of recesses **217** in the procedure sheath **216**. The locking arrangement between the biased fingers **215** and matching recesses **217** may fix the position of the housing **252** relative to the procedure sheath **216**.

Following deployment of the anchor **208**, the housing **252** and the procedure sheath **216** are withdrawn together. Withdrawing the housing **252** causes the anchor **208** to anchor itself within the vessel **228** against the vessel wall **234** as shown in FIGS. **5**B-**5**C. Further withdrawing the housing **252** causes the automatic driving assembly **260** to slide forward in the housing **252** as shown in FIG. **5**D-**5**E. Functionally, the anchor **208**, sealing plug **210**, carrier tube **202**, procedure sheath **216**, and automatic driving assembly **260** maintain the same axial position upon this further withdrawal of the housing **252**, and the procedure sheath **216** and housing **252** move proximally (see FIGS. **5**D-**5**E).

Referring to FIGS. **5**D-**5**E, the distal end portion **207** of the carrier tube **202** is exposed within the percutaneous incision **219** as the housing **252** and the procedure sheath **216** are retracted. The carrier tube **202** may retain its position relative to the tissue puncture **218** until the housing **252** and the procedure sheath **216** have been retracted a predetermined distance. Relative movement between the housing **252**/procedure sheath **216** and the carrier tube **202** may be facilitated by a sliding mount arrangement between the automatic driving assembly **260** and the housing **252**. However, according to some embodiments the automatic driving assembly **260** is fixed to the housing **252**.

As shown by the combination of FIGS. **5**B-**5**I, the automatic driving assembly **260**, which is attached to the carrier tube **202**, may be free floating or displaceable and slides relative to the housing **252** as the housing **252** and the procedure sheath **216** are retracted. However, the automatic driving assembly **260** may be initially held in a first position relative to the housing **252**, as shown in FIG. **5**B. For example, as shown in FIG. **5**B, the automatic driving assembly **260** may comprise a temporary holder such as a stowage detent **255** slidingly mounted in a track. The track is shown in FIG. **5**B as a webbing track **253**. The webbing track **253** is disposed in the housing **252**. The stowage detent **255** may include a finger **257** with a protrusion to at least temporarily hold the automatic driving assembly **260** in the first position shown in FIG. **5**B, and prevent premature sliding within the housing **252**.

Although the finger **257** tends to hold or temporarily lock the automatic driving assembly **260** in the first position shown in FIG. **5**B, the finger **257** releases when a sufficient force is applied between the housing **252** and the automatic driving assembly **260**. For example, with the anchor **208** deployed, a retraction force provided by a user to the housing **252** causes the finger **257** to deflect inward and release. Thereafter, the finger **257** provides very little resistance to sliding movement between the automatic driving assembly **260** and the housing **252**. Accordingly, retraction of the housing **252** may retract the procedure sheath **216**, which is fixedly connected to the housing **252**, but the automatic driving assembly **260** and the carrier tube **202** may slide relative to the housing **252** and therefore remain in position with respect to the tissue puncture **218**, as shown in FIG. **5**D. The automatic driving assembly **260** may slide a predetermined distance with respect to the housing **252** until the automatic driving assembly **260** reaches a stop. The predetermined distance may be at least long enough to fully expose the slit **209** (see FIG. **5**A) in the carrier tube **202** to facilitate later removal of the sealing plug **210** from the carrier tube **202**.

When the automatic driving assembly **260** reaches the stop, further retraction of the housing **252** withdraws the carrier tube **202** as well, ejecting the sealing plug **210** automatically, as shown in FIGS. **5**F-**5**G. The spool **266** begins to rotate to permit unwinding of some of the suture **204** from the spool. Typically, the driving plate **264**, which rotates with the spool **266**, unwinds an amount that does not initiate advancing of the compaction tube driver **272** and compaction tube **212**. The driver follower **274** of the compaction tube driver **272** may track along that portion of the cam surface **276** that has a constant radius (see FIG. **5**F), thereby avoiding substantial advancing of the compaction tube driver **272**.

Still further retraction of the housing **252** further rotates the spool **266** and driving plate **264** to contact the variable radius portion (i.e., the increased radius portion) of the cam surface **276** with the driver follower **274** to advance the compaction tube driver **272**. Advancing the compaction tube driver **272** advances the compaction tube **212** to compact the sealing plug **210** toward the anchor **208** (see FIGS. **5**H-**5**I). Upon completion of compacting the sealing plug **210**, the operator may actuate the release member **270** to permit unwinding of the suture **204** from the spool **266** so that the suture **204** may be cut near the tissue layer **230** to release the housing **252** from the anchor **208**/sealing plug **210**.

Unlike previous closure devices that require a separate, manual compaction procedure following the deposition of the sealing plug **210**, the closure device **200** of the present disclosure automatically compacts the sealing plug **210** by applying a retracting force to the housing **252**. The sealing plug **210** may be compacted during or after withdrawal of the carrier tube **202**, reducing or eliminating gaps that may otherwise occur between the sealing plug **210** and the tissue puncture **218** in the vessel **228**.

In addition, by placing tension on or pulling the suture **204** away from the percutaneous incision **219**, the suture **204** may cinch and lock (with a slip knot or the like) together the anchor **208** and the sealing plug **210**, sandwiching the vessel wall **234** between the anchor **208** and sealing plug **210**. The force exerted by the compaction tube **212** and the cinching together of the anchor **208** and sealing plug **210** by the suture **204** also causes the sealing plug **210** to deform radially outward within the percutaneous incision **219** and function as an anchor on the proximal side of the tissue puncture **218** as shown in FIGS. **5**H-**5**I.

The compaction tube **212** is automatically driven toward the sealing plug **210** by the automatic driving assembly **260**. The driving plate **264** of the automatic driving assembly **260** is shown in further detail in FIGS. **6**A-**6**C. The driving plate **264** advances the compaction tube driver **272** by contact between the cam surface **276** and the driver follower **274**. Other arrangements are possible for transferring the rotational motion of the driving plate **264** to a linear force in the compaction tube driver **272**. The use of a driver follower **274** extending from the end of an elongate compaction tube driver **272** and arranged to contact a cam surface **276** along a periphery of a driving plate **264** is merely exemplary. In other arrangements, the compaction tube driver **272** may be permanently connected to the driving plate **264**. The driving plate **264** may be directly connected to the compaction tube **212**. Generally, any device or construction that uses of a cam structure driven by rotation of a spool member (about which the suture is wound) either directly or indirectly to advance a compaction member to compact a sealing plug falls within the spirit and scope of the present disclosure.

In some arrangements, the automatic driving assembly may include a gear assembly or additional structure interposed between the spool member and driving plate. In some examples, the spool member and driving plate are not arranged coaxially. As such the driving plate may be indirectly driven or rotated by the spool member.

In embodiments including the clutch **268**, the clutch **268** may comprise a plurality of release fingers **261** as shown in FIG. **5**A. The release fingers **261** are arranged substantially in a circle. A first component **263** of the release fingers **261** is cantilevered from a base **265** and extends normal therefrom. A protrusion **267** of the first component **263** extends radially outward and is received by a mating internal recess **269** of the spool **266**. A second component **271** of the release fingers **261** arcs substantially normal to the first component **263** and the base **265**. The second component **271** of each of the release fingers **261** extends through a central hole **273** of the spool **266**. The release member **270** fits over and contacts the second components **271** of each of the release fingers **261**.

The fit of the protrusions **267** of the base **265** with the mating recesses **269** of the spool **266** causes the base **265** (and thus the driving plate **264** to which the base **265** is fixedly attached) and spool **266** to rotate together at an identical angular velocity. However, when the release member **270** is depressed, the release member **270** slides along the arcs of the second component **271**, forcing each of the release fingers **261** radially inward. The radial inward displacement of the release fingers **261** at least partially removes the protrusions **267** from the mating recesses **269**, allowing independent rotation of the spool **266** with respect to the driving plate **264**. Therefore, after the sealing plug **210** is driven toward the anchor **208**, the selectably disengagable automatic driving assembly **260** is disengaged or disabled, allowing the suture **204** to safely unwind without further compaction. The suture **204** is then exposed to the operator for convenient cutting.

Another embodiment of the a driving plate **364** is illustrated in FIGS. **7** and **8**A-**8**C. The driving plate **364** includes a cam slot **378** that defines at least one cam surface **376**. The cam slot **378** may have a shape that mirrors a cam shape of another portion of the driving plate **364**, such as an outer periphery surface of the driving plate **364**. Alternatively, the cam slot **378** may have a unique shape and size from the outer periphery shape of the driving plate **364**. The cam slot **378** may have any shape, curvature, and length to provide the desired linear movement of the compaction tube driver **272** at a given rotated position of the driving plate **264**.

The driver follower **274** of the compaction tube driver **272** may be inserted into the cam slot **378** and arranged in contact with at least one of the internal cam surfaces **376** defined along a length of the cam slot **378**. Rotation of the driving plate **364**, as shown in FIGS. **8**A-**8**C, eventually advances the compaction tube driver **272**. The use of a cam slot **378** may promote a more secure connection or interface between the compaction tube driver **272** and the driving plate **364**.

Another embodiment of the a driving plate **464** and compaction tube driver **472** is illustrated in FIG. **9**. The driving plate **464** includes a cam surface **476** and may be constructed similar to the driving plate **264** described above. The compaction tube driver **472** may include a clutch member **473** that limits overcompaction of the sealing plug of the tissue puncture closure device. The clutch member **473** may include, for example and without limitation, a biasing member such as a compression spring. The clutch member **473** may be positioned at any location along the length of the compaction tube driver **472**, or along a length of the compaction tube or other feature driven by or integrated into the compaction tube driver **472**. Multiple clutch members **473** may be used in series or in parallel to provide a clutch function in the compaction tube driver **472**.

The compaction tube driver **472** may include a driver follower **474**. The driver follower **474** may include a friction reducing member **475** that limits or reduces friction at an interface between the compaction tube driver **472** and the driving plate **464**. In one arrangement, the friction reducing member **475** may include a roller, low friction pad, or bearing member of any shape, size or construction.

Operation of the embodiment of FIGS. **5**A-**6**C is as follows with similar operation possible for the embodiment of FIGS. **8**A-C. As the housing **252** of the closing device **200** is retracted from the percutaneous incision **219** with the anchor **208** secured within the vessel **228**, as shown in FIG. **5**B, the stowage detent **255** releases. The automatic driving assembly **260** and carrier tube **202** may remain stationary and therefore float relative to the housing **252**. The procedure sheath **216** is retracted as the housing **252** is withdrawn, exposing the distal end portion **207** of the carrier tube **202**. The automatic driving assembly **260** eventually contacts a stop (or, in some embodiments, the automatic driving assembly is fixed), and further retraction causes the automatic driving assembly **260** and carrier tube **202** to retract as well. As the automatic driving assembly **260** retracts, the suture **204**, which is threaded through the anchor **208**, unwinds from and causes rotation of the spool **266**. The spool **266** drives the driving plate **264** as the spool **266** rotates via a coaxial connection therebetween.

As the driving plate **264** rotates, the cam surface **276** of the driving plate **264** contacts the driver follower **274** of the compaction tube driver **272** to drive the compaction tube **212**. In some arrangements, the compaction tube driver **272** may be long enough and constructed such that it functions as the compaction tube **212**. The compaction tube **212** compacts the sealing plug **210**.

Therefore, as the closing device **200** is retracted from the percutaneous incision **219**, the procedure sheath **216** may be retracted (see FIGS. **5**D-**5**E), the carrier tube may be retracted (see FIGS. **5**F-**5**G), and the sealing plug **210** is automatically compacted (see FIGS. **5**H-**5**I). The sealing plug **210** is more likely to create a sufficient vascular seal without a gap relative to the anchor **208**, as may otherwise occur with a separate manual compaction procedure.

Moreover, when the sealing plug **210** has been sufficiently compacted, the automatic driving assembly **260** may be disengaged, enabling further retraction of the closure device **200** without additional compaction. With the sealing plug **210** fully compacted, there may be little or no portion of the suture **204** extending outside of the tissue layer **230** and exposed to an operator. Therefore, it may be difficult for an operator to separate the sealing plug **210** and anchor **208** from the remainder of the closure device **200**. In addition, too much retraction with the selectably automatic driving assembly **260** enabled could potentially overcompact the sealing plug **210** into the vessel **228**. Accordingly, the automatic driving assembly **260** may be advantageously disabled by activating the release member **270** through the release member opening **251**. Activating the release member **270** allows the suture **204** to fully unwind from the spool **266** without driving the compaction tube **212**. Unwinding the spool **266** exposes a sufficient length of the suture **204** to allow an operator to easily cut the suture **204** and separate the sealing plug **210** and anchor **208** from the remainder of the closure device **200**.

The preceding description has been presented only to illustrate and describe exemplary embodiments of the present disclosure. It is not intended to be exhaustive or to limit the invention to any precise form disclosed. Many modifications and variations are possible in light of the above teaching. It is intended that the scope of the invention be defined by the following claims.

What is claimed is:

1. A tissue puncture closure device, comprising:
an anchor;
a sealing plug;
a filament positioned between the sealing plug and the anchor;
a compaction member assembly structured and arranged to apply an axially directed compressive force to automatically compact the sealing plug toward the anchor, the compaction member assembly having a distal end and a proximal end;
a spool having a portion of the filament wound thereon;
an eccentric cam, the cam being eccentrically mounted relative to the spool, the cam having a cam surface portion, the cam surface portion being eccentric relative to a rotation axis of the cam, the cam surface portion being arranged to contact the compaction member assembly upon rotation of the spool to advance the distal end of the compaction member assembly.

2. A tissue puncture closure device according to claim **1** wherein the cam surface portion is defined around a periphery of the cam.

3. A tissue puncture closure device according to claim **1** wherein the cam surface portion is defined within a slot feature of the cam.

4. A tissue puncture closure device according to claim **1** wherein the compaction member assembly further includes a drive follower positioned at the proximal end of the compaction member assembly and exposed for contact by the cam surface portion.

5. A tissue puncture closure device according to claim **1** wherein the compaction member assembly includes a compaction tube and a compaction tube driver arranged end-to-end, the compaction tube defining the distal end of the compaction member assembly.

6. A tissue puncture closure device according to claim **1** wherein the cam surface portion includes a constant radius portion and a variable radius portion.

7. A tissue puncture closure device for partial insertion into and sealing of a tissue puncture in an internal tissue wall accessible through a percutaneous incision, comprising:
an anchor for disposition on a distal side of the internal tissue wall;
a sealing plug for disposition on a proximal side of the internal tissue wall;
a filament connected to and anchored at a distal end to the anchor and sealing plug, the sealing plug being slidable and cinchable along the filament toward the anchor to close the tissue puncture;
a compaction assembly disposed on the filament and arranged to drive the sealing plug along the filament distally towards the anchor; the compaction assembly having a proximal end
a storage spool onto which a proximal end of the filament is wound;
an eccentric cam, the cam being eccentrically mounted relative to the storage spool, the cam having a cam surface arranged to apply a variable driving force to the

proximal end of the compaction assembly upon rotation of the storage spool, the cam surface being eccentric relative to a rotation axis of the cam.

8. A tissue puncture closure device of claim **7** wherein the cam is connected to the storage spool by a releasable clutch.

9. A tissue puncture closure device of claim **7** wherein the cam surface comprises a constant radius portion and a variable radius portion.

10. A tissue puncture closure device of claim **7** wherein the storage spool and cam are arranged coaxially.

11. A tissue puncture closure device of claim **7** wherein the cam is coupled to the compaction assembly.

12. A tissue puncture closure device of claim **7** wherein withdrawal of the tissue puncture closure device from the tissue puncture with the anchor bearing against the internal tissue wall unwinds the filament from the storage spool.

13. A tissue puncture closure device of claim **12**, wherein the storage spool rotates the cam, and the cam drives the compaction assembly to directly or indirectly provide a compaction force to the sealing plug.

14. A tissue puncture closure device of claim **7**, wherein the cam surface directly contacts the compaction assembly.

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